UPCOMING CHANGES TO THE FORMAT OF INFORMED CONSENT DOCUMENTS

The changes to regulations on human subjects research, set to begin in January 2018, have a new requirement about how informed consent documents are formatted. The government recognizes that lengthy, complex consent forms are not organized in a way that helps people understand why they might or might not want to participate.

When the new rules go into effect, each consent form will begin with a ‘concise summary’ of key information that is most likely to help a person make a decision about joining the study.

A national workgroup, funded by NIH, is hoping to give guidance to researchers about the types of information that should be included in the concise summary. They suggest the concise summary could be written to answer topics such as:

- What problem is this study trying to solve?
- What are the pros and cons of being in this study?
- What is the difference between being in this study and continuing on with usual care?
- What else should I consider as I make my decision? (This might include other aspects of a particular study that participants need to know, such as particularly burdensome procedures or time commitments, costs, etc.)

Discussion questions for the LEC

What do you consider to be the “key information” that patients use to decide whether or not to participate?

What is the most useful format for presenting this information?

What questions do you ask an investigator as you are making your decision?

What do you see as the pros and cons of being in research?

How can we help investigators do a better job of answering questions during the consenting process?
REFERENCE: Typical Topics in Clinical Trial Consent Forms

- Introduction: (this is research, it’s voluntary)
- Reason for the invitation/ the condition under study
- Purpose of the study
- Duration of the study
- Number of participants to be enrolled
- Description of the drug, device or treatment being tested
- Description of study groups and randomization, if applicable
- Study visits and procedures
- Risks to participants
- Pregnancy risks
- Benefits
- Costs to participants
- Payments for participation
- Contact in case of injury
- Potential for payment in case of injury
- Alternatives to research participation
- Privacy protections
- Participant’s right to withdraw
- Caveat that investigator, sponsor or FDA could stop the study
- Assurance of notifying participants with significant new findings
- Study team contact phone for questions about the study
- IRB contact phone for questions about participant rights
- Optional aspects such as optional DNA testing, optional biopsies, future research
- Funding source for the project
- Information on researcher conflicts of interest, if applicable
- Link to clinicaltrials.gov
- Other study-specific topics such as protections against genetic discrimination, commercial value of study samples, requests to follow pregnant partners, federal protections for sensitive study data
Smoking Cessation Study

Example of a Concise Summary Added to an Existing Consent Document

(No Headers)
CONCISE SUMMARY FOR #1602 NOLLEN

We’re doing a research study for African American smokers who don’t smoke every day. African Americans seem to have a harder time quitting in general, and even people who don’t smoke every day can have trouble quitting. We are trying to find ways to help this group of smokers be successful.

We are doing a study at our Swope Parkway Clinic. People in the study will come to the clinic for 5 visits over a six month period.

Everyone in the study will get 5 counseling sessions with counselors who are specially trained to help you quit.

Additionally, some people in the study will have access to nicotine replacement therapy (NRT) with their choice of the patch, gum or lozenges. Your assignment to either get NRT plus counseling or counseling only will be random, like flipping a coin. 2/3 of the people in the study will have receive NRT and 1/3 will receive counseling only.

There are a few steps to find out if you are eligible to join the study. We’ll ask you questions about your current smoking habits and your health and medications. We will do a urine test to make sure you’re not pregnant and to see what level of nicotine is in your body right now.

Your assignment to get NRT plus counseling or counseling only will be decided at your first study visit after we confirm that you are eligible to join.

Counseling and NRT have been shown to be effective in helping people quit, and quitting smoking is one of the best things you can do for your health. The counseling and the NRT (if you receive NRT) will be provided at no cost.

You should be aware that quitting smoking can be very difficult. We would expect that you will have withdrawal symptoms and cravings. People who are quitting tend to have less energy for awhile, and you may be more irritable than usual. Your counselor will help you identify strategies for getting you through these times of craving and withdrawal during regularly scheduled sessions. You can also call your counselor or the study coordinator at any time if you have questions or problems.

It is important for you to have enough information to decide whether or not you want to join our study. We will discuss the details in this consent form with you. We will answer all your questions to help you decide. Please ask as many questions as you need to.

If you are able to come to the study visits at Swope Health Central over the next six months and you want to hear more about being in the study, we will go over the details in the rest of this consent form. You don’t have to make your decision today. You can find out about the study now, and then we will call you in the next few days to see if you are interested in finding out if you are eligible.
You are being asked to join a research study. Participating in research is different from getting standard medical care. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC), Swope Health Services, and other participating hospitals or clinics.

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or at any time during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

This research study will be performed by KUMC with Dr. Nikki Nollen as the researcher. About 384 people will be enrolled in the study.

Why am I being asked to take part in this study?
You are being asked to take part in this study because you are an African American who is a non-daily smoker, which means you smoke on some but not all days.

Why is this study being done?
Non-daily smokers represent a growing number of racial/ethnic minority smokers. Non-daily smokers are still at increased risk for smoking-related medical problems, like heart disease and lung cancer, compared to non-smokers.

One out of 4 African Americans is a non-daily smoker. African Americans seem to have a harder time quitting and have worse medical problems related to smoking even at lighter usage rates compared to Whites.

Current tobacco treatment guidelines target daily smokers and generally recommend counseling and medications to aid in quitting. However, there are no guidelines...
specifically for non-daily smokers. This study will allow the researchers to explore treatment options for non-daily smokers and find out if some treatments work better than others.

What is being tested in this study?
The researchers are testing if counseling alone or counseling plus over-the-counter nicotine replacement therapies (NRT), like the patch, gum, or lozenge, helps non-daily smokers quit smoking.

How long will I be in the study?
You will be in the study for approximately 6 months. You will be asked to visit the clinic 5 times and talk with the study team over the phone 4 times.

What will I be asked to do?
The study will be explained to you. The study team will go over this consent form with you in detail and answer all of your questions. If you would like to participate in the study, you will be asked to sign and date this consent form. You will get a signed copy of this consent.

You will be randomly assigned by chance (like flipping a coin) to one of the following study treatment groups:
- Group 1: Counseling only, 5 sessions over 12 weeks
- Group 2: Counseling plus NRT, 5 sessions over 12 weeks plus 12 weeks of NRT

You have a 33% (1 out of 3) chance of being assigned to the counseling only group and a 67% (2 out of 3) chance of being assigned to the counseling plus NRT group.

Below, you will find a schedule of events listing all procedures that will occur at each study visit.

<table>
<thead>
<tr>
<th>Schedule of Events</th>
<th>Week 0</th>
<th>Week 1</th>
<th>Week 4</th>
<th>Week 8</th>
<th>Week 10</th>
<th>Week 12</th>
<th>Week 26</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smoking history/demographics</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy test</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Counseling session</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urine sample</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Surveys</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Receive supply of nicotine replacement therapy</td>
<td>✓</td>
<td>✓**</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Approximate amount of time for study visit</td>
<td>2 h</td>
<td>30 m</td>
<td>15 m</td>
<td>15 m</td>
<td>15 m</td>
<td>15 m</td>
<td>1 h</td>
</tr>
</tbody>
</table>

**Receive supply by mail
Non-daily smokers

**Smoking history/demographics:** You will be asked questions about your smoking history such as age of initiation, type of cigarette, and quitting history, as well as demographics such as age, marital status, and education level.

**Pregnancy test:** If you are a woman able to have children, you will be asked to take a pregnancy test. You cannot participate in this study if you are pregnant.

**Counseling session:** You will participate in a 15-30 minute counseling session to help you quit smoking. Your counseling sessions will be recorded. The reason for recording is to make sure you are receiving counseling that fits your unique needs. The recording will be identified by a number, not your name, and no one other than the study team will have access to the recording. Your recording will be kept for 15 years. After that, it will be destroyed.

**Urine sample:** You will be asked to provide a urine sample. The sample will be used to test for nicotine and other chemicals found in cigarettes.

**Surveys:** You will be asked about your smoking status, use of NRT, symptoms commonly associated with quitting smoking or using NRT that you may be experiencing, and about factors that make it harder or easier to quit smoking.

**Receive supply of nicotine replacement therapy:** The study will provide the NRT if you are assigned to the counseling plus NRT treatment group. You will be advised on what dose to take.

You will first have a 9 day trial period to figure out which type of NRT works best for you. You will be given a 3 day supply each of nicotine gum, patches, and lozenges to try. Nicotine gum and lozenges release nicotine into the mouth. Nicotine patches stick to your skin and release nicotine through the skin into your bloodstream. At the Week 1 phone call, you will be asked to pick the NRT for you and the study team will mail you a 3-4 week supply. You will receive additional NRT at the Week 4 and 8 in-person study visits.

**What are the possible risks or discomforts?**

Treatment with NRT may cause side effects or other problems. The researchers will ask you about any side effects you are experiencing throughout the study. You should also tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects. You may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.

**Nicotine Replacement Therapy Risks**

Risks for participating in the study are primarily those related to the use of nicotine replacement therapy. Nicotine replacement therapy, particularly in continuing smokers, can be associated with:
Non-daily smokers

Nicotine Lozenge

- Nausea (17%)
- Hiccups (11%)
- Headache (9%)
- Constant heartburn or indigestion (7%)
- Irregular or fast heartbeat (6%)

- Vomiting (5%)
- Diarrhea (5%)
- Dizziness (4%)
- Sore throat or mouth problems (4%)
- Change in taste (3%)
- Stomach pain (3%)

Nicotine Gum

- Nausea (16%)
- Headache (10%)
- Heartburn/indigestion (9%)
- Hiccups (7%)
- Mouth, tooth, or jaw problems (6%)
- Diarrhea (6%)
- Fast, pounding, or irregular heartbeat (6%)
- Sore throat (5%)

- Blisters in the mouth (5%)
- Dizziness (5%)
- Vomiting (2%)
- Change in taste (2%)
- Stomach pain (2%)
- Burping (1%)
- Increased saliva (<1%)
- Trouble sleeping (<1%)
- Irritability (<1%)

Nicotine Patch

- Sweating (31%)
- Redness or swelling at the patch site (25%)
- Irritability (22%)
- Problems sleeping or vivid dreams (19%)
- Headache (10%)
- Dizziness (7%)

- Nausea or vomiting (5%)
- Abnormal heartbeat or rhythm (5%)
- Diarrhea (4%)
- Nervousness or restlessness (4%)
- Difficulty breathing (3%)
- Tiredness (2%)

To address these concerns, you will be given information along with guidance from your counselor. Call the study team if you experience any of these side effects during the study so that they can help you to manage the symptoms or reduce your nicotine dose, if needed.

Symptoms of nicotine overdose
In addition to the symptoms listed above, you could experience any of the following, which might be a sign of a nicotine overdose.

- Mental confusion or weakness
- Extreme paleness
- Cold sweats
- Disturbed hearing or vision

Please contact the study team if you have any of these or other side effects during the study.
Non-daily smokers

Allergic Reaction Risks
Sometimes, people have serious allergic reactions to drugs. A severe allergic reaction could be life-threatening and may result in death. Symptoms of allergic reactions include:

- swelling of the mouth, throat or eyes
- rash
- difficulty breathing
- coughing
- wheezing
- sudden drop of blood pressure
- seizures
- flushing
- a fast pulse
- sweating

You should call 911 if you think you are having a severe allergic reaction. Please also contact the study team if you have any of these or other side effects during the study.

Questionnaire Risks
There is a risk of feeling uncomfortable while answering some of the questions in the questionnaires. If you feel uncomfortable at any time you may skip a question or stop participating all together.

Pregnancy Risks
Treatment with NRT might hurt an unborn child or a child who is breast-feeding. You cannot be in this study if you are pregnant or nursing a baby. You cannot be in this study if you are trying to get pregnant. If you are a female who can have children then you will have a pregnancy test before the study starts. If you are a female able to get pregnant, you must use an effective method of birth control while you are in the study. The approved methods of birth control are abstinence, the pill, contraceptive ring (NuvaRing), shot or injection (Depo-Provera), patch (Ortho Evra), IUD (Mirana), implant (Implanon), or barrier method such as a diaphragm with intravaginal spermicide, cervical cap, or a male or female condom.

There may be pregnancy risks that are not known yet. For this reason, you must tell the researcher right away if you get pregnant during the study.

Are there benefits to being in this study?
You may or may not benefit from this study. Quitting smoking is one of the best things you can do for your health, regardless of whether you participate in this study. Those who do not quit smoking may not benefit from this study. Researchers hope that the information from this research study may be useful in improving treatment for non-daily smokers.

Will it cost anything to be in the study?
The study will pay for all study-related medical services provided during this study. These services include NRT supply (if applicable), study visits, and study-related procedures such as the counseling sessions and urine lab tests as listed in this consent form.
Any other medical visits and procedures you have outside of the study due to other standard of care treatments or other health issues are billable to you or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

Your insurance may not cover some or all of the standard care services if you are part of a research study. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study. Some procedures require Pre-Certification from your insurance company. Pre-Certification is not a guarantee of payment.

You can still be in the study even if your insurance denies coverage for your standard of care treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who qualify. If your insurance denies coverage and you do not qualify for the financial assistance, you will be charged for all bills that are not the responsibility of the study. The study team will be able to provide more information to you.

**Will I get paid to participate in the study?**
You will receive payment for participation in this study as outlined in the table below. You may receive up to $180.00 if you complete all study visits as shown in the chart below.

<table>
<thead>
<tr>
<th>Week 0</th>
<th>Week 1</th>
<th>Week 4*</th>
<th>Week 8*</th>
<th>Week 10</th>
<th>Week 12</th>
<th>Week 26</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>$40</td>
<td>$20</td>
<td>$20</td>
<td>$20</td>
<td>$20</td>
<td>$40</td>
<td>$20</td>
<td>$180</td>
</tr>
</tbody>
</table>

*payment will be posted after completion of both the phone call and in-person visit

You are also eligible to receive $20 for each person you refer who is eligible for and enrolls in this study. You are allowed to refer up to 3 different people for an additional total payment of $60.

You will be given a ClinCard, which works like a debit card. After a study visit or referral enrolls in this study, payment will be added onto your card by computer. The money will be available within 1-2 business days. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are $600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the
computer after the study is over and the money on the card has been used. Your
information will not be shared with other businesses. It will be kept completely
confidential.

This study includes providing specimens to the researcher. The specimens will belong
to the University of Kansas Medical Center. There are no plans for you to profit from any
new products that are developed from research done on your specimens.

**Will the researchers get paid for doing the study?**
The research team and the institution (KUMC Research Institute, Inc.) will receive
payments from the funding source, Patient Centered Outcome Research Institute, for
conducting this study. Payments will be used for research purposes only.

**What happens if I get hurt or sick during the study?**
If you have a serious side effect or other problem during this study, you should
immediately call your study counselor at the number they have provided. The counselor
will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be
provided for you at the usual charge. Treatment may include first aid, emergency care
and follow-up care, as needed. Claims will be submitted to your health insurance policy,
your government program, or other third party, but you will be billed for the costs that
are not covered by the insurance. You do not give up any legal rights by signing this
form.

If you think you have been harmed as a result of participating in research at the
University of Kansas Medical Center (KUMC), you should contact the Director, Human
Research Protection Program, Mail Stop #1032, University of Kansas Medical Center,
3901 Rainbow Blvd., Kansas City, KS 66160. Under certain conditions, Kansas state
law or the Kansas Tort Claims Act may allow payment to persons who are injured in
research at KUMC.

**Do I have to be in the study?**
Being in research is voluntary. You can choose whether or not to participate. Even if
you decide not to join the study, you can still come to KUMC for services and treatment.

**What other choices do I have?**
You can choose not to be in the study. Instead of being in this study, you can receive
treatment that is already available. Other available treatments include: quitting cold
turkey, using other smoking cessation programs, purchasing nicotine gum, lozenge or
patches, obtaining a prescription for nicotine inhaler, nasal spray, bupropion, or Chantix
from your doctor, or calling a quit line to receive counseling to help you quit smoking.
You can access NRT products and counseling even if you decide not to participate in
this study.
How will my privacy be protected?
The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities. You may be identified by information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KUMC by Dr. Nollen, members of the research team, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Nollen and the research team permission to share information about you with persons or groups outside KUMC. Your information will be shared with representatives of the University of Minnesota and the University of California – San Francisco, the laboratory that processes study lab samples, and U.S. agencies that oversee human research (if a study audit is performed). These groups or agencies may make copies of study records for audit purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of the study treatment.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely.

While you are participating in this study, you may see and copy any study information that is placed in your study record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally
Non-daily smokers

refuse to disclose information that may identify you in any federal, state, local, civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Finally, the investigator is not prevented from taking steps, including reporting to the proper authorities, to prevent serious harm to you or others and instances of child abuse.

**Can I stop being in the study?**

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC or Swope Health Services.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Nikki Nollen. The mailing address is Dr. Nikki Nollen, University of Kansas Medical Center, 3901 Rainbow Boulevard, Mail Stop 1056, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about side effects of NRT and to ensure your safety. They may use and share information that was gathered before they received your cancellation.

**Could my participation be stopped early?**

This study might be stopped, without your consent, by the investigator. Your participation also might be stopped by the investigator if it is in your best interest or if you do not follow the study requirements.

Neither the investigator nor the University of Kansas Medical Center will be obligated to provide you with any treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

**Who can I talk to about the study?**

Before you sign this form, Dr. Nikki Nollen or other members of the study team should
Non-daily smokers

answer all your questions. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

CONSENT
Dr. Nikki Nollen or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered. 
You will be given a signed copy of the consent form to keep for your records.

____________________________________
Print Participant’s Name

____________________________________
Signature of Participant   Time Date

____________________________________
Print Name of Person Obtaining Consent

____________________________________
Signature of Person Obtaining Consent   Date
Non-daily smokers

PERMISSION TO BE CONTACTED ABOUT FUTURE STUDIES
I give permission to be contacted about future studies that might require more information:

YES          NO

About smoking       ☐      ☐
About any other health related issues ☐      ☐

_____________________________    _________________    _________
Participant – Print Name          Signature               Date

_____________________________    _________________    _________
Person Obtaining Consent –       Person Obtaining Consent Signature Date
   Print Name

KUMC IRB # STUDY00001602 | Approval Period 6/27/2017 – 6/26/2018 | FWA# 00003411
OPTIONAL SAMPLE STORAGE AND FUTURE USE
You are being asked to allow any left-over urine samples to be stored for future research. If you agree, your samples will be used for future research studies involving smoking and its impact on the human body.

The samples will be stored at research laboratories at KUMC. Your samples will be stored by a unique code and no personal identifying information will be included with them. Your samples will be stored indefinitely and will not be shared with researchers outside the study.

No additional risks are expected from research being conducted on the samples because the samples have already been collected.

The information about the uses and disclosures of your health information for the main study also apply to this additional testing. You may choose not to participate in optional sample storage and future use, while still participating in the main study. You may also withdraw your consent to store your samples for future research at any time.

You and your doctor will not receive the results of future testing. The results will not be put in your medical record.

Please mark your choice “Yes” or “No” below. If you have any questions you can talk to the investigator or the study team.

☐ Yes, I agree to allow the investigator to store my left-over urine samples for future research on smoking

☐ No, I do not agree to allow the investigator to store my left-over urine samples for future research on smoking

____________________________________    _______ __________________
Print Participant's Name      Signature of Participant      Time Date

____________________________________ __________________
Print Name of Person Obtaining Consent   Signature of Person Obtaining Consent      Date
Antibiotics Study

Example of a Concise Summary Added to an Existing Consent Document

With Headers
Study Title: The Comparison of Outcomes of Antibiotic Drugs and Appendectomy Trial

Principal Investigator:

You are being invited to participate in this research study because you have appendicitis. Whether or not you decide to participate is up to you. In order to make that decision it is important that you have enough information to decide. Before making a decision we will discuss the study and all of the information in this consent form with you and answer any questions you may have.

What problem is the study trying to solve?

In the United States appendicitis is commonly treated with surgery to remove the appendix. In Europe appendicitis is commonly treated with antibiotics. We are doing this research study to answer the question, do antibiotics treat appendicitis as well as surgery. If the answer is yes, people may be able to avoid surgery and a hospital stay.

What is the difference between being in this study and getting usual care?

If you are in this study you will be assigned, by chance, like the flip of a coin, to either have your appendicitis treated with surgery or antibiotics. If you do not participate in this study you will have surgery to remove your appendix.

Appendicitis is usually very painful and requires immediate attention. Surgery provides immediate and permanent relief, but involves time in the hospital, anesthesia and about a week of recovery time before returning to normal activities. Antibiotics can usually be given without being in the hospital, but the pain will not immediately go away, appendicitis may return and surgery may still be needed.

Why might someone consider joining this study?

Some people may join the study hoping to be in the group that gets antibiotics. Being in the antibiotic group will allow them to avoid having surgery and anesthesia and the need to immediately postpone everything they have scheduled for the next week to allow for recovery time.

Study-specific things to consider:

People in the antibiotic group will have to take antibiotics for 10 days. The antibiotics might cause problems like an allergic reaction or diarrhea. People in the surgery group will have surgery as soon as possible and will get immediate relief, but will have to stay in the hospital overnight.
CONSENT TO PARTICIPATE IN RESEARCH

______________________ (name of institution)

Study Title: The Comparison of Outcomes of Antibiotic Drugs and Appendectomy Trial

Principal Investigator: ____________________________

Introduction

You are being invited to be in this experimental research study because you have appendicitis. Appendicitis is most likely caused by bacteria that grow and collect in the appendix, causing pain and swelling. The appendix is a small tube about three inches long that is attached to your intestine and is located in the right lower area of your stomach.

This study is comparing outcomes of two accepted treatments for appendicitis – one that is commonly used in Europe (antibiotics) and one that is commonly used in the United States (appendectomy). The most common treatment for appendicitis in the United States and at this institution is an appendectomy, a surgical procedure to remove the appendix. During an appendectomy, people are given anesthesia (medication that will put them to sleep), and the treating doctors remove the appendix. The operation can be done with three small incisions (cuts) on the skin using instruments that are guided by a camera – this is called laparoscopic appendectomy. The operation can also be done with a single incision called an open appendectomy. If you have surgery, the treating doctor will discuss these two approaches. You will sign a separate consent document for surgery. The operation usually takes about an hour. You may feel groggy in the hours after surgery. Most patients do well and go home the next day, but some people stay longer due to complications of the surgery or because of other reasons. Most people eat and drink shortly after the surgery and return to normal activities after a week or so.

In this study participants taking antibiotics for appendicitis will receive at least one dose of intravenous (through the vein) antibiotics followed by oral (taken by mouth) antibiotics for a total of 10 days. After that first dose of intravenous antibiotics, some people may be able to leave the emergency department and go home for the rest of their antibiotics treatment. Others will be admitted to the hospital for another day of intravenous antibiotics. The participant and the treating doctor will decide whether or not the participant is admitted to the hospital or can go home from the emergency department.
Purpose

We are doing this study to compare 2 treatments for acute appendicitis: 10 days of antibiotics and surgery. Although appendectomy and antibiotics for appendicitis have both been studied before and found to be safe, this is the first randomized study to be conducted in the United States to look at patient reported outcomes and rates of success with the antibiotic treatment in avoiding appendectomy.

Procedures

If you agree to participate in this study, we will collect information about your illness tests, and treatments performed during your hospital stay. We will also ask you to complete questionnaires about the treatment you received, your current health status, and your quality of life. These questionnaires will be asked at 9 different time points over the next two years. At the end of the two-year follow-up, we may contact you to ask if you would be willing to participate in a longer-term study with yearly surveys. In addition, we would like to use some of the information collected about you for this study for future research related to understanding the characteristics of surgical patients (across many types of surgeries) and their outcomes. The questionnaires will take about 20 minutes to complete.

You will be randomly assigned by chance, like the flip of a coin, to one of the following groups:

Group A: receives surgical treatment (appendectomy)
Group B: receives antibiotics treatment

If the signs and symptoms of appendicitis are not improving enough after 48 hours with the antibiotics, then your treating doctor may recommend surgery to remove the appendix. No matter what treatment you receive, we will control your pain and make sure you can eat and take your medications before you go home.

Neither you nor your study doctor will know ahead of time what group you will be in.

Group A: Surgical

If you are in this group, you will receive antibiotics, and an appendectomy will be done.

Group B: Antibiotic

If you are in this group, you will receive antibiotics for 10 days:

- At least one dose of intravenous (through the vein) antibiotics
- Followed by oral antibiotics for the remainder of the 10 days
**Follow-up**

You will be contacted by phone once a week for two weeks, and you will be asked to complete a short questionnaire over the phone with a research coordinator at _______________. The questionnaire will ask you to answer questions about your appendicitis symptoms, your medication use, and if you have returned to see a doctor. The questionnaire will take about 10 minutes to complete.

You will also be contacted by at week 4, 3 months, 6 months, 9 months, 12 months, 18 months, and 24 months after you enroll in the study, by a research member at _______________. Study staff will contact you by phone, mail, email, or text message, based on the contact information you provide. The questionnaires may be completed by phone, by mail, or online. They will ask you questions about your quality of life and experience as a patient with appendicitis, pain level and severity, symptoms, treatment satisfaction, and your ability to return to your daily routine. It will take about 20 minutes to answer each questionnaire.

During the study, you will be monitored for complications and other illnesses in addition to appendicitis. We would like to record information from your medical records. We will record information about you before and after your treatment date and other information like your age, insurance status, and smoking history. We will also record information that your treating doctors record in your medical record including your medical history, laboratory and imaging tests, medications you are taking, information about your treatments, hospitalizations and any clinical outcomes that occur after your treatment. If you visited another facility for care related to your appendicitis during the study, you may be asked to provide your consent to release those medical records to the study team. While we will only contact you for up to two years to complete questionnaires, we may continue to collect information from your health records up until the end of the study.

The information that you provide in these follow-up questionnaires is confidential and will not be shared with your treating doctor unless you report any symptoms suggesting appendicitis-related health concerns.

**Length of study participation**

Your participation in this study will last up to 2 years.

**Risks**

**Surgery**
- Bleeding
- Wound infection
- Pain
- Scarring
• Problems from anesthesia (putting you to sleep for surgery)

If you will be having surgery for your appendicitis, then the surgeons will explain the possible risks in detail and will get your consent for surgery as they normally would.

**Antibiotics**

• Allergic reactions (sometimes severe)
• Diarrhea

Your specific medication regimen and its side effects will be discussed with you by your treating physician.

Prior studies have shown that antibiotics treatment of appendicitis without surgery is safe, but on average, previous studies show that 25% or 1 in 4 patients treated this way go on to have an appendectomy in the next year. In other studies, most of these surgeries occurred in the first few weeks after the antibiotics treatment was started. Some patients had surgery because the appendicitis did not get better with antibiotics alone, and some got better but had symptoms of appendicitis again later.

Antibiotics are also given routinely for appendicitis, even when it is treated with surgery. The antibiotics used in this study have risks that are similar to the antibiotics you would be receiving even if you do not participate in the study.

In prior studies of antibiotics treatment of appendicitis, there was no higher rate of a ruptured (“burst”) appendix in patients who had antibiotics only and complications did not happen more often when compared to the surgery patients. Because of small numbers of patients in these studies, we cannot say for sure whether the risk is greater or not in one group or the other. One study found a slightly greater rate of infection in the abdomen with antibiotics treatment, but the difference was not considered significant. An analysis of all studies of antibiotics vs. surgery for appendicitis found that patients treated with antibiotics alone had nearly half the complications of the surgery group as well as less pain and faster recovery time than the surgery group.

One advantage of surgery is that very rarely when surgeons look inside your abdomen they find unrelated problems in your internal organs. This might mean that your surgeon identifies a mass or cancer in another organ (e.g., liver) or even in the appendix itself (about 1 in 200 appendix removals identify some mass of the appendix). If we treat patients with antibiotics only (without surgery), we might “miss” the opportunity to see another problem that we did not expect to find (such as a small mass that cannot be seen in the computed tomography (CT) scan or ultrasound test you had in the diagnosis of appendicitis).
We do not know how your body might respond to the medications or procedures used in this study. We will discuss the risks identified above with you and the chances that they will happen. There may be risks that we do not know about at this time. Unknown problems, ranging from a mild inconvenience to some severe enough to result in death may occur.

If you experience any problems you should report them immediately to the study doctor, _______________. After hours, please call _______________ and tell the operator to page the doctor on call for _______________.

**Benefits**

You will not receive a direct benefit from being in this research study. We hope to learn information that may help others in the future.

**Alternatives**

If you choose not to participate, you and your treating doctor will discuss the best way to treat your appendicitis.

**Costs**

There will not be additional costs to you if you participate in this study. The medical care that you will receive in this study is considered standard care for your situation and would be recommended whether or not you participate in this study. These costs will be billed to you or your insurance carrier.

**Research-related injury**

In the case of injury or illness resulting from your participation in this study, medical treatment is available to you at ______________. You will be charged the usual and customary charges for any such treatment you receive.

**Compensation**

You will receive up to $125 for completing the questionnaires related to the study. You will receive $20 for the first questionnaire, $10 each for the Week 1 and 2 questionnaires, $20 for the Week 4 questionnaire, $10 each for months 3, 6, 9, 12, $10 for the 18-month questionnaire, and $15 for the final 24-month questionnaire.
**Voluntary Participation**

Your participation is voluntary. If you decide not to participate in this study you will not suffer a penalty or loss of benefits to which you are otherwise entitled.

**Withdrawal**

You may choose to stop your participation in this study at any time. If you decide to withdraw the information already collected about you may still be used in this study but additional information will not be collected. Your decision to stop your participation will have no effect on the quality of medical care you receive at ________________.

The study doctor can remove you from the study if you become ineligible to participate, the study is suspended or cancelled, or if you do not follow instructions.

**Confidentiality**

Every effort will be made to keep the information we learn about you private. Study personnel, ________________ (the study sponsor), ________ (the study funding agency), the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP) and the ________________ Institutional Review Board (IRB) and Office of Integrity and Compliance, and Grants and Contracts may review the study records. Study data may be submitted to regulatory agencies in other countries but you will not be identified. If study results are published your name will not be used.

A copy of this informed consent document will be filed in your medical record because the experimental research you are agreeing to participate in involves your care, diagnosis, or treatment.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your de-identified research information will be combined into a database, which also has de-identified information of research participants enrolled nationwide in this study. The Data Coordinating Center located at ____________ will store information that can identify you in a separate, secure location and will not share that information with anyone.
Protected Health Information

Protected health information is any personal health information through which you can be identified. The information collected in this study includes: your name, medical record number, phone number, mailing address, email, information in your medical records such as race, sex, medical history, diagnosis, vital signs, treatments, physician notes, and test results. By signing this consent document, you authorize __________ and his staff to collect this information and use your records as necessary for this study. The study doctor and the study sponsor, _____________________, will use your information to look at results for the study.

The information collected for this study will be kept until the study is complete and may be combined with information collected through other research studies or used in other studies but no information will identify you. While this study is ongoing you may not have access to the research information, but you may request it after the research is completed.

Your medical information and records, once disclosed, may be re-disclosed and may no longer be protected by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA), which is a federal regulation designed to protect medical information, including medical information and records created through research.

You have the right to cancel this authorization at any time by providing the study doctor with a written request to cancel the authorization. If you cancel this authorization medical information and records about you that were created before the authorization was cancelled will still be used and disclosed as needed to preserve the integrity of the study.

This authorization has no expiration date. If you do not sign this consent document, you will not be allowed to participate in this study.

Number of Participants

We expect 100 participants to enroll in this study here and 1,552 nationwide.

Questions

If you have questions about this study or need to report any problems, side effects, or injuries, please call ______ at 601-984-5443. After hours and on weekends please call the operator at 601-984-1001 and ask for the doctor on call for ________.

You may discuss your rights as a research participant with __________. The Institutional Review Board is a group of people not involved with this study who have reviewed the study to protect your rights.

You will be given a copy of this consent document for your records after it has been signed.
Statement of Participation

I have been told about this study, including the experimental treatment I may receive, and the possible risks and benefits. I agree to participate in this study, to follow instructions, and to report any side effects to my study doctor. My participation is voluntary and I may withdraw at any time without any penalty or loss of benefits to which I am entitled, including medical care at ______________.

By signing this form I am not giving up any legal rights may have.

________________________________
Participant’s Printed Name

________________________________
Participant’s Signature

________________________________
Date

__________________________________________
Printed Name of Person Obtaining Consent

__________________________________________
Signature of Person Obtaining Consent

________________________________
Date

I acknowledge that the participant identified above has been entered into this study, with properly obtained informed consent.

________________________________
Signature of Investigator

________________________________
Date
Heart Study

Example of a consent form that begins with the concise summary information and then continues with the rest of the document, rather than having separate introduction page.
Consent and Authorization Document

SUMMARY OF THE STUDY
You are invited to participate in a research study because you have been diagnosed with one of the following conditions:

- Acute or chronic systolic heart failure with possible need for or existing use of mechanical circulatory support (MCS)
- Pulmonary Hypertension
- Acute or chronic heart failure with preserved ejection fraction (HFpEF)
- Severe aortic stenosis with plan for transcatheter aortic valve replacement (TAVR)

This form will describe the research project and your role as a participant. One of the investigators or research staff will answer any questions you may have about this form and about the study. Please read carefully and do not hesitate to ask anything about the information provided below.

What problem is this study trying to solve?
The purpose of this study is to better understand these heart problems and the treatments patients receive.

What is the difference between joining the study and not joining?
If you join the study, we will perform some measurements of your heart and how the blood flows through it. For some people in the study, these extra measurements will be made during your normal heart catheterization procedure. For other people, we will need to perform the heart catheterization procedure as part of the study. If you don’t join the study, you will get your normal heart care and monitoring from your doctor.

What are the benefits to me if I join this study?
This research may not benefit or help you directly, but we hope this will help make treatments better in the future for other patients.

What are the inconveniences or risks to me if I join this study?
For some people, the extra measurements will cause your normal heart catheterization procedure to take a little longer. For other people, you will have to take the time to have a heart catheterization for the study. Heart catheterizations can have health risks. You can read more about these risks in this document.

Do I have to be in this research study?
Research studies include only people who choose to take part. You can tell us that you don’t want to be in this study. You can start the study and then choose to stop the study later. We will still give you medical care and answer any questions you have. Your decision will not affect your relationship with your doctor or the study team in any way.
PERSON TO CONTACT
If you have any questions, complaints or concerns during normal business hour, please call the study physician Dr. Frederick Welt at (801) 213-4060. If you need to contact us after normal business hours, a 24-hour emergency number is (801) 581-2121. You may ask to have Dr. Welt paged.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

STUDY PROCEDURES
The research team at University of Utah will oversee this project. If you participate in this study, here is what will happen:

- We will collect and use medical information about you. This includes things like general health measurements, diagnoses, treatments, and test results. Some of this information will come from your normal medical record.

- We will perform a heart conductance catheterization procedure. More details about this procedure are described below.

Heart Conductance Catheterization
This procedure will help us understand the way your heart works and how the blood flows through different parts of your heart.

You will receive an injection of numbing medication near the artery in the wrist or groin. A catheter will then be inserted into the artery and will be guided by a cardiologist with use of X-ray into the heart. While in the heart, the catheter will take multiple measurements to help better understand your cardiac function. After removal of the catheter, care will be taken to ensure proper healing of the artery. If performed in the artery in the wrist, a wristband will be used to compress this area. If performed in the artery in the groin, one of our interventional cardiologists may put a stitch or a plug in the artery to ensure proper healing.

If you are already scheduled to receive a heart catheterization for your normal care, we will perform the research measurements at the same time. This means that we will not need to make an extra needle stick to insert the catheter for the study. But if you are not scheduled for this procedure for your normal care, we would do the procedure for the study only.
**RISKS**
These are the risks we know for this study. There may be other risks that we do not know about.

**Catheterization.** There is a risk from the insertion of the conductance catheter through an arterial access into the heart. Possible complications include local vascular injury, bleeding from the access site, infection, arrhythmia, cardiac perforation, stroke, myocardial infarction, and death.

**Radiation.** The catheterization procedures will use fluoroscopy imaging to help the physician to see what is happening in your heart. Fluoroscopy uses X-rays that will expose you to some radiation. You will be exposed to some extra radiation if you are in this study, because we will need it during the research part of the catheterization. If you are already scheduled to receive a heart catheterization for your normal care, the extra radiation will be in addition to what is used during the normal procedure.

The risk from this radiation exposure is considered to be small and comparable to other every day risks. To give you an idea of how much radiation you will receive, we will compare this radiation to the radiation that you receive from natural sources. Everyone receives a small amount of unavoidable radiation every day. Some of this radiation comes from space while some comes from radiation that is naturally occurring in water, soil, rocks and minerals found in plants and animals. If participating in this project the excess radiation that you will be exposed to in this research study can range from 0.4 – 3.3 mSv. This highest radiation dose is equivalent to about 13 months of natural background radiation. This amount does not include any radiation exposures that you may receive from other tests as part of your medical care.

**RESEARCH-RELATED INJURY**
If you are injured from being in this study, medical care is available to you at the University of Utah as it is to all sick or injured people. The University of Utah has not set aside any money to pay the costs for such care. The University will work with you to address costs from injuries. Costs would be charged to you or your insurance company (if you have insurance), to the study sponsor or other third party (if applicable), to the extent those parties are responsible for paying for medical care you receive. Since this is a research study, some health insurance plans may not pay for the costs. By signing this consent form you are not giving up your right to pursue legal action against any parties involved with this research.

The University of Utah is a part of the government. If you are injured in this study, and want to sue the University or the doctors, nurses, students, or other people who work for the University, special laws may apply. The Governmental Immunity Act of Utah is a law that controls when a person needs to bring a claim against the government, and limits the amount of money a person may recover. See sections 63G -7-101 to -904 of the Utah Code.

**RIGHT OF INVESTIGATOR TO WITHDRAW**
You may be removed from the study without your consent at any time. Reasons why you may be removed from the study include, but are not limited to:
• Your study doctor determines that it is in your best interest not to take part;
• The study is stopped by your hospital, or by the health authorities.

COSTS AND COMPENSATION TO PARTICIPANTS
Your normal heart catheterization procedures are not part of the research and will be billed to you and/or your insurance. All of the treatments and tests that you receive for your normal care will also be billed to you and/or your insurance.

You will not be charged, nor will your insurance company be charged, for a heart conductance catheterization procedure that is only being done as part of this study.

You will not be paid for participation in this study.

NUMBER OF PARTICIPANTS
We expect to enroll 200 patients at the University of Utah.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION
Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study.

This is the information we will use and include in our research records:
• Demographic and identifying information like name, sex, age, address, telephone number, and email address
• Related medical information about you like family medical history, allergies, current and past medications or therapies, and information from physical examinations, such as blood pressure reading, heart rate, temperature, and lab results
• All tests and procedures that will be performed in the study

How we will protect and share your information:
• We will do everything we can to keep your information private but we cannot guarantee this. Study information will be kept in a secured manner and electronic records will be password protected. Study information may be stored with other information in your medical record. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

• In order to conduct this study and make sure it is conducted as described in this form, the research records may be used and reviewed by others who are working with us on this research:
  o Members of the research team and University of Utah Health Sciences Center;
  o The University of Utah Institutional Review Board (IRB), who reviews research involving people to make sure the study protects your rights;
If we share your information with groups outside of University of Utah Health Sciences Center, we will not share your name or identifying information. We will label your information with a code number, so they will not know your identity.

What if I decide to Not Participate after I sign the Consent and Authorization Form?
You can tell us anytime that you do not want to be in this study and do not want us to use your health information. You can also tell us in writing. If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research. This authorization does not have an expiration date.

If you change your mind, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research. This authorization does not have an expiration date.

CONSENT
I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I will be given a signed copy of the consent and authorization form to keep.

I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

________________________
Participant’s Name

________________________ ____________________
Participant’s Signature Date

________________________
Name of Person Obtaining Authorization and Consent

________________________ ____________________
Signature of Person Obtaining Authorization and Consent Date